

In the Claims:

1. (currently amended) A method for determining the total amount of an analyte anti-HER2 antibody in a fluid sample in the presence of ~~an interfering substance~~ HER2 extracellular domain (ECD), comprising:
- (a) providing a solid surface dual-coated with a first antibody recognizing said analyte anti-HER2 antibody as in a free analyte- form and a second antibody recognizing said ~~interfering substance~~ HER2 ECD when bound to said analyte anti-HER2 antibody;
- (b) contacting said dual-coated surface with said fluid sample, whereby said first antibody binds said free analyte anti-HER2 antibody and said second antibody binds said ~~interfering substance~~ HER2 ECD bound to said analyte anti-HER2 antibody; and
- (c) determining the total amount of said free analyte anti-HER2 antibody and said analyte anti-HER2 antibody bound to said ~~interfering substance~~ HER2 ECD by contacting the product of step (b) with a detectably labeled secondary antibody recognizing said analyte anti-HER2 antibody, wherein said detectably labeled secondary antibody recognizes an epitope which is different from the epitope recognized by said first antibody and is also different from the epitope recognized by said ~~interfering substance~~ HER2 ECD, and
- wherein the total amount of said free anti-HER2 antibody and said anti-HER2 antibody bound to said HER2 ECD is compared with a standard curve generated by using various concentrations of said purified anti-HER2 antibody in place of said fluid sample in step (b).

2.-3. ~~(canceled)~~.

2 4. (original) The method of claim 1, wherein said first and second antibodies are polyclonal antibodies.

3 5. (original) The method of claim 1, wherein said first and second antibodies are monoclonal antibodies.

~~4.~~ ~~(canceled)~~.

4 ~~7~~. (currently amended) The method of claim ~~2~~ ¹, wherein said detectable label is an enzyme conjugated to said secondary antibody.

5 ~~8~~. (original) The method of claim ~~7~~ ⁴, wherein said enzyme is peroxidase.

6 ~~9~~. (original) The method of claim ~~8~~ ⁵, wherein said peroxidase is horseradish peroxidase.

7 ~~10~~. (original) The method of claim ~~7~~ ⁴, wherein said enzyme is alkaline phosphatase.

8 ~~11~~. (original) The method of claim ~~7~~ ⁴, wherein said enzyme is detected using a substrate for said enzyme.

9 ~~12~~. (original) The method of claim ~~11~~ ⁸, wherein said substrate is ortho-phenylene diamine (OPD) for the detection of said peroxidase.

10 ~~13~~. (original) The method of claim 1, wherein said solid surface is in a configuration of a test tube, a well, a bead, a rod, or a strip.

11 ~~14~~. (original) The method of claim ~~13~~ ¹⁰, wherein said configured solid surface is glass, plastic, or paper.

12 ~~15~~. (original) The method of claim ~~14~~ ¹¹, wherein said plastic is polystyrene or polyacrylate.

13 ~~16~~. (original) The method of claim 1, wherein said fluid sample comprises a biological fluid.

14 ~~17~~. (original) The method of claim ~~16~~ ¹³, wherein said biological fluid comprises serum or plasma.

18.-35. (canceled)

¹⁵ 36. (currently amended) The method of claim 35 ¹, wherein said anti-HER2 antibody is a murine monoclonal antibody.

¹⁶ 37. (original) The method of claim ¹⁵ 36, wherein said murine anti-HER2 monoclonal antibody is 4D5.

¹⁶ 38. (original) The method of claim ¹⁶ 37, wherein said anti-HER2 murine monoclonal antibody is a humanized version of recombinant 4D5 antibody.

¹⁸ 39. (currently amended) The method of claim ¹⁷ 38, wherein said humanized version of recombinant 4D5 anti-HER2 antibody is ~~trastuzumab (HERCEPTIN®)~~ huMAb4D5-8 (rhuMAb HER2).

40. (canceled)

¹⁹ 41. (currently amended) The method of claim ¹⁸ 40 ³⁶, wherein said first antibody recognizes ~~trastuzumab (HERCEPTIN®)~~ huMAb4D5-8 (rhuMAb HER2) and does not significantly cross-react with human IgG, and said second antibody against HER2 ECD is a polyclonal or a monoclonal antibody.

²⁰ 42. (currently amended) The method of claim ¹⁹ 41, wherein said first antibody recognizing ~~trastuzumab (HERCEPTIN®)~~ huMAb4D5-8 (rhuMAb HER2) is a monoclonal antibody or a fragment derived therefrom, and said monoclonal antibody against HER2 ECD is

7C2. (~~ATCC~~ ATCC 48-12215)

43. (canceled)

⁴⁴
~~36-39~~ 44. (currently amended) The method according to any one of the claims 35
36-39, wherein said fluid sample is serum or plasma derived from a cancer patient undergoing
anti-HER2 therapy.

²¹
22/45. (original) The method of claim 44, wherein said cancer is breast cancer
overexpressing HER2.

46.-62. (canceled)